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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,243	01/04/2002	Paul I. Freimuth	BSA 01-22	6646

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BROOKHAVEN SCIENCE ASSOCIATES/
BROOKHAVEN NATIONAL LABORATORY
BLDG. 475D - P.O. BOX 5000
UPTON, NY 11973

EXAMINER

AKHAVAN, RAMIN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Applicant 06/28/04 *ks***Office Action Summary**

Application No.

10/037,243

Applicant(s)

FREIMUTH ET AL.

Examiner

Ramin (Ray) Akhavan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-86 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
|---|--|

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-13, 77-78 and 80, drawn to a method of enhancing solubility and adoption of native folding conformation for a protein where a peptide extension is positioned at the carboxy terminal of the protein, where the extension confers a self-chaperoning activity, classified in class 435, subclass 69.7.
2. Claims 14-25, 77, 79 and 81, drawn to a method of enhancing solubility and adoption of native folding conformation for a protein where a peptide extension is positioned at the amino terminal of the protein, where the extension confers a self-chaperoning activity, classified in class 435, subclass 69.7.
3. Claims 26-39 and 82, drawn to a method of enhancing *in vitro* renaturation of a protein that otherwise persists substantially in inclusion bodies, where a protein extension is positioned at the carboxy terminal of the protein, classified in class 435, subclass 69.7.
4. Claims 40-52 and 83, drawn to a method of enhancing *in vitro* renaturation of a protein that otherwise persists substantially in inclusion bodies, where a protein extension is positioned at the amino terminal of the protein, classified in class 435, subclass 69.7.
5. Claims 53-64, drawn to an expression vector comprising a fusion construct encoding a peptide extension fused to the carboxy end of a protein, classified in class 435, subclass 320.1.

6. Claims 65-76, drawn to an expression vector comprising a fusion construct encoding a peptide extension fused to the amino terminal end of a protein, classified in class 435, subclass 320.1.

7-33. Claims 84-86, drawn to antibodies, which bind specifically any of the peptides encoded by SEQ ID NOs: 5-25 and 27-33, where each peptide represents a separate group, classified in class 424, subclass 130.1.

There are 33 groups from which applicant must elect a single group to be examined on the merits. Inventions in Groups 1-2 as compared to Groups 3-4 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group 1 or 2 are not capable of use together with Group 3 or 4, because renaturation from inclusion bodies is a wholly separate biological process, that cannot occur in concert with expressing proteins in cells, where the proteins are *soluble* and adopt native folding characteristics. It logically follows, that the Groups 1-2 as compared to Groups 3-4 necessarily have different modes of operation, outcomes or effects. In the instant case the different inventions in the inventions are related through a general concept but are biologically and patentably distinct.

As between groups drawn to extensions placed at the amino end (Groups 2 and 4) versus carboxy end of proteins (Groups 1 and 3), each group inheres a distinct structure to function correlation. For example, the solubility for an amino-extended protein versus carboxy-extended protein would not necessarily be the same. Furthermore, the vector constructs are structurally

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and functionally distinct. Therefore the groups are distinguishable based on structural, biological thus patentably distinct characteristics.

Group 7-33 are biologically and patentably distinct from the preceding groups because antibodies are not necessarily involved to any extent in the groups drawn to methods of protein expression or groups drawn to the vector compositions of Groups 5-6. The vectors are clearly not necessarily linked to the antibodies of Groups 7-33. For example, the antibodies can be raised against peptides that are chemically synthesized. In addition, each antibody is structurally and functionally distinct as compared to any other antibody. The structural difference manifests itself through the functional differential (i.e. binding specificity) particular to each

Inventions in Groups 1-4 and Groups 5-6 are related as process and apparatus for its practice respectively. In other words the groups drawn to the methods of protein expression are the processes and the expression vectors are the apparatuses. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the vectors can be used in disparate processes, such as gene knockouts through homologous recombination (e.g. through sequences encoding the protein of interest).

In addition, this application contains claims directed to the following patentably distinct species: various peptide extensions as depicted in SEQ ID NOs: 5-33.

Where a group is elected which contains a claim drawn to a multitude of different peptide extensions species (i.e. different SEQ ID NOs), Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be

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restricted if no generic claim is finally held to be allowable. Currently, claims 13, 25, 37, 52, 64, 76 and 84 are generic in that each is drawn to a multitude of patentably distinct species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Furthermore, claim 77 links inventions in Group 1 and 2. The restriction requirement for the linked inventions is subject to nonallowance of the linking claim 77. Upon allowance of the linking claim, the restriction requirement as to the linked invention shall be withdrawn and any claims linking depending from or otherwise including all the limitations of the allowable linking claim is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double

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patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

For the reasons given above these inventions are distinct and have acquired a separate status in the art as shown by their different classification. In addition each group would require a separate search, thus restriction for examination purposes as indicated is proper. Applicant is advised that a reply to this restriction requirement must include an election for the invention (i.e. Group 1 or 2 or 3, etc.) to be examined, for the reply to be complete, notwithstanding that the requirement be traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if none or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

The claims encompass 33 distinct inventions, from which applicant must choose one, notwithstanding traverse.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramin (Ray) Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached on Monday- Friday from 8:00-4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can

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be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


GERRY LEFFERS
PRIMARY EXAMINER